



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Neutralizing Antibodies to Influenza HA and Their Use and Identification

Description of Technology:

The effectiveness of current influenza vaccines varies by strain and season, in part because influenza viruses continuously evolve to evade human immune responses. While

the majority of seasonal influenza infections cause relatively mild symptoms, each year influenza virus infections result in over 500,000 hospitalizations in the United States and Europe. Current standard of care for individuals hospitalized with uncomplicated influenza infection is administration of neuraminidase inhibitors. However, frequent use of such antiviral drugs increases the risk that the virus will develop drug resistance, especially in high-risk populations. Thus, alternative strategies are required to protect or treat vulnerable populations who have been hospitalized with severe influenza.

Using a combination of recombinant proteins and sophisticated flow cytometry, scientists at NIAID isolated families of antibodies capable of neutralizing diverse group 1 and group 2 influenza A viruses. Specifically, the families of antibodies identified precisely target parts of the hemagglutinin (HA) protein, present on the surface of the influenza virus, that are least variable from season to season (Joyce, M.G., et al. Cell (2016) 166 (3): 609-623). Therefore, it is hypothesized that passive administration of members of these families of antibodies to individuals would represent an alternative to the current standard of care for severe influenza virus infection. Additionally, these families of antibodies could be useful for development of a product aimed at conferring passive immunity in vulnerable populations during the time of an outbreak or emergence of a pandemic strain of influenza

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

NIAID is continuing development of these neutralizing antibodies to influenza toward a clinical product for treatment and/or prevention of influenza virus infection.

Consequently, for some fields of use, NIAID will evaluate a license applicant's capabilities and experience in advancing similar technologies through the regulatory process.

Potential Commercial Applications:

- Prevention of influenza A virus infection
- Therapeutic intervention to treat influenza infection

Competitive Advantages:

- Ability to potently neutralize both group 1 and group 2 influenza A strains

Development Stage:

- Proof of concept in animal models

Inventors: Adrian McDermott (NIAID), Peter Kwong (NIAID), John Mascola (NIAID), M. Gordon Joyce (NIAID), Robert Bailer (NIAID), Sarah Andrews (NIAID), Paul Thomas (NIAID), Gwo-Yu Chuang (NIAID), Adam Wheatley (NIAID), Yi Zhang (NIAID), James Whittle (NIAID).

Publications: Joyce, M.G., et al. Cell (2016) 166 (3): 609-623

Intellectual Property: HHS Reference No. E-061-2016 - US Patent Application No. 62/330,837 filed May 2, 2016; Patent Cooperation Treaty Application No. PCT/US2017/030641 filed May 2, 2017.

Licensing Contact: Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize influenza

monoclonal antibody technologies. For collaboration opportunities, please contact Dr.
Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

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Suzanne Frisbie

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

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